

**Notice of Allowability**

Application No.

10/780,103

Examiner

Sabiha Qazi

Applicant(s)

DELUCA ET AL.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/20/2005.
2. ☒ The allowed claim(s) is/are 49, 54-59 and 64-69 and 74-79, 84-88 (re-numbered as 1-24).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

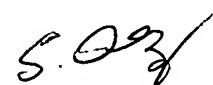
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_

  
SABIHA QAZI, PH.D  
PRIMARY EXAMINER

### REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance:
2. Claims 49, 54-59 and 64-69 and 74-79, 84-88 (re-numbered as 1-24) is allowed. The closest prior art is DeLuca et al., US 5,843,928. The reference does not teach nor suggest the method of use of the compounds as presently claimed.

The claims 49 and 54-58 are drawn to a method of treating a cancerous disease selected from a group consisting of leukemia, colon cancer, breast cancer, and prostate cancer comprising administering to a patient with said disease an effective amount of 20(S)-1alpha, 25-dihydroxy-z-methylene-26,27-dihomo-19-nor vitamin D3 and its analogues one of them having the following structure (claim 49).

Instant claims differ from the copending application in having 1 methyl group more at 26,27 position. The compound of Application '990 is a homologue of the presently claimed invention.

The comparative data and unexpected results presented in Remarks filed on 12/20/2005, 7/21/2005 and the exhibits clearly show and explains the differences between 2-methylene-19-nor-20(S)-1alpha,25-dihydroxy vitamin D3 (2MD) and presently claimed method of using 26, 27 dihomom compound. The ED50 for 2MD is  $1.5 \times 10^{-10}$  while ED50 of 26, 27 dihomom compound is  $2.6 \times 10^{-11}$  which is approximately ten times more effective than 2MD at cellular differentiation, and would be therefore unexpectedly better compound for the treatment.

These results were unexpected and would not have been obvious by routine experimentation. Applicants have clearly demonstrated that the activities of these two homologues were unexpected. The presently claimed method of 26, 27 dihomom showed

Art Unit: 1616

significantly greater intestinal Ca transport as well as other difference therefore, invention of claims 12-22 of copending Application No. 10/669,990 would not have been obvious to one skilled in the art, as these were not expected by the routine experimentation.

Examiner thanks Attorney Dr. Thomas M. Wozny for his extended cooperation during the prosecution of this application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### **Contact Information**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan, Sreeni (acting) can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1616

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR System, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 23, 2006

  
SABIHA QAZI, PH.D  
PRIMARY EXAMINER